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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,806	12/03/2003	Benjamin F. James IV	IND-38DIV	4108
27777	7590	08/24/2005	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			BLEVINS, JERRY M	
			ART UNIT	PAPER NUMBER
			2883	

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/726,806	JAMES ET AL.	
	Examiner	Art Unit	
	Jerry Martin Blevins	2883	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-24 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-24 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date, _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 05/15/2005 have been fully considered but they are not persuasive.

With regards to applicant's arguments with respect to 102 rejections of claims 15, 16, and 30, examiner points out that US Patent to Dalton, cited in previous action, teaches an association of the proximal end of the fiber cores with an optical connector, particularly in column 9 line 55 – column 10, line 9. Dalton also teaches an optical fiber core in a continuous, uninterrupted sleeve, as demonstrated in Figure 1. Given that Dalton explicitly teaches that the sleeve extends at least from the proximal end to the distal face of the optical fiber core, Figure 1, and the association of the proximal end of the fiber cores with an optical connector, examiner concludes that Dalton impliedly teaches that the sleeve extends from the connector (connected at the proximal end) to at least the distal end of the core.

With regards to applicant's arguments with respect to 103 rejections of claims 24 and 29, examiner points out that US Patent to Thielen, cited in previous action, also teaches forming a closed tissue penetrating tip, as particularly seen in the abstract and Figure 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-21, 23, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Dalton.

Regarding claims 15, 16, and 30, Dalton discloses a method of forming a medical device comprising the steps of: providing an optical fiber core having a proximal end and a distal face; associating the proximal end of the core with an optical connector; enclosing the fiber core in a continuous light transmitting sleeve by extending the sleeve distally of the distal face of the optical fiber core, wherein the sleeve has a length at least substantially the length of the optical fiber core extending from the optical connector to at least the distal face of the optical fiber core (Figure 1, column 8, lines 28-38 and column 9, lines 61-67).

Regarding claims 17-19, Dalton also teaches forming a tip in the sleeve, the tip being disposed distal of the distal face of the optical fiber core (column 13, line 7 – column 14, line 18), wherein a space is provided intermediate the distal face of the optical fiber core and the sleeve tip (Figures 3a, 3b).

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Regarding claims 20 and 21, Dalton also teaches disposing a light scattering component in the space provided intermediate the distal face of the optical fiber core and the sleeve tip (Figure 1 and column 10, lines 10-25).

Regarding claim 23, Dalton also teaches that the step of enclosing the optical fiber core in the sleeve results in the sleeve touching the core (Figures 4 and 5).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dalton.

Regarding claim 22, Dalton as discussed above discloses the method of making a device. Dalton, however, does not disclose that the method includes the step of abrading a portion of the inner surface of the sleeve. As disclosed in page 2 of the specification of the present application, it is known to abrade the sleeve in order to conduct light from an optical coupling layer to the exterior. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Dalton to include the step of abrading a portion of the inner surface of the sleeve. The motivation would have been to improve conduction of light from the optical coupling layer to the exterior.

Claims 24, 26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thielen.

Regarding claim 24, Thielen discloses a method of making a device comprising the steps of: exposing a distal portion of an optical fiber; providing an optical coupling

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layer intermediate the distal portion of the optical fiber core and the sleeve; and forming a closed, tissue penetrating tip disposed distal of the distal portion of the fiber core (abstract, column 2, lines 43-45 and 64-66, column 3, lines 25-27, and Figure 1).

Regarding claim 26, Thielen further teaches providing a space intermediate the distal face of the optical fiber core and the tissue penetrating tip (Figure 1).

Regarding claim 29, Thielen as discussed above discloses the method of making a device. Thielen, however, does not disclose that the method includes the step of abrading a portion of the inner surface of the sleeve. As disclosed in page 2 of the specification of the present application, it is known to abrade the sleeve in order to conduct light from an optical coupling layer to the exterior. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Thielen to include the step of abrading a portion of the inner surface of the sleeve. The motivation would have been to improve conduction of light from the optical coupling layer to the exterior.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thielen in view of US Patent to Ohtsu et al., number 5,908,562.

Regarding claim 27, Thielen teaches the limitations of the base claim 24. Thielen does not teach disposing a material having fluorescent properties intermediate the distal face of the optical fiber core and the tip. Ohtsu teaches disposing a material having fluorescent properties intermediate a distal face of an optical fiber core and a tip (column 2, lines 17-30). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Thielen to include the teaching of Ohtsu. The

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motivation would have been to improve detection of the penetrated tissue (Ohtsu, column 2, lines 31-43).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thielen in view of Dalton.

Regarding claim 28, Thielen teaches the limitations of the base claim 24. Thielen does not teach contacting the fiber optic core with the sleeve. Dalton teaches contacting a fiber optic core with a sleeve (Figures 4 and 5). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Thielen to include the teaching of Dalton. The motivation would have been to improve protection of the core.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-24, 26-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-9 of U.S.

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Patent No. 6,522,806. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 15-21, 23, 24, 26-28, and 30 merely recite the structure recited in claims 1-4 and 6-9 of U.S. Patent No. 6,522,806. For example, claim 15 of the present application and claim 1 of U.S. Patent No. 6,522,806 disclose a medical device comprising: an optical fiber core having a proximal end associated with an optical connector and a distal face, and a continuous, uninterrupted sleeve having a length at least substantially the length of the optical fiber core extending from the optical connector to at least the distal face of the optical fiber core. Furthermore, claims 22 and 29 of the present application and claim 4 of U.S. Patent No. 6,522,806 each teach a step of abrading a portion of an inner surface of the sleeve.

Conclusion

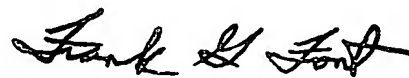
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Martin Blevins whose telephone number is 571-272-8581. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frank G. Font can be reached on 571-272-2415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMB



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